REMARKS

Reconsideration and withdrawal of the rejections of the application is respectfully requested in view of the remarks herein.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-17 are now pending. Claims 1-6, 8, 13 and 15 are amended herein, and new claim 18 is added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended claims is found throughout the specification.

II. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claim 1 was rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Office Action alleged that the claim could be interpreted as three separate inventions. Applicants respectfully traverse.

Claim 1 has been amended herein to refer to a first composition consisting essentially of an isolated coagulation factor IXa and a second composition consisting essentially of an isolated coagulation factor VIII. Accordingly, it is respectfully submitted that claim 1 now clearly relates to two compositions which can be administered (1) simultaneously, wherein, e.g., the two compositions are admixed prior to being administered, (2) simultaneously and separately, wherein, e.g., the two compositions are administered at the same time but are not mixed prior to administration, or (3) sequentially, wherein, e.g., the two compositions are each administered with some amount of time passing between the administration of the first and second compositions. Accordingly, it is respectfully submitted that the claimed invention of two

compositions is clear and definite as described in claim 1. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is therefore respectfully requested.

Claims 4 and 13 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for the improper use of acronyms. The rejection is respectfully traversed. It is respectfully submitted that the amendments herein have introduced the full names of the coagulation factors into the claims, thereby obviating the rejection. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1, 2 and 4-8 were rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The rejection is respectfully traversed.

Specifically, claim 1 was considered indefinite because there allegedly is nothing linking the two compositions. Applicants respectfully disagree. As described previously, the first and second compositions of claim 1 are to be used together via administration that is: (1) simultaneous, wherein, e.g., the two compositions are admixed prior to being administered, (2) simultaneous and separate, wherein, e.g., the two compositions are administered at the same time but are not mixed prior to administration, or (3) sequential, wherein, e.g., the two compositions are each administered with some amount of time passing between the administration of the first and second compositions. Accordingly, the use of the compositions, as recited in the claim, provides the link between the compositions.

Claim 2 was rejected because the term "admixing" "does not explain with a clarity how to use the invention 'in the preparation of a composition of claim 1'." It is respectfully submitted that the claim has now been amended to recite a method of making a composition of new claim 18, which claim recites a composition comprising the first composition according to claim 1 and the second composition according to claim 1. Accordingly, the rejection as to claim 2 is now moot.

Claims 4-8 were rejected as lacking method steps related to using factor IXa in the manufacture of a composition comprising factor VIII. Claim 4 has been amended herein to recite a method of treating haemophilia A or haemophilia B, comprising administering to a subject in need thereof a composition consisting essentially of coagulation factors VIII and IXa. Accordingly, claim 4 now contains the step of administering a composition to a patient in need

thereof, and claims 5-8 further limit the method by reciting additional limitations to the subject and the composition that is administered. Accordingly, the rejection is now moot.

Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

III. THE REJECTIONS UNDER 35 U.S.C. §101 ARE OVERCOME

Claims 1-3 were rejected under 35 U.S.C. §101 as referring to a product of nature. The rejection is respectfully traversed. It is respectfully submitted that the amendment herein has added the limitation that the coagulation factors are isolated, and therefore are not products of nature, such that the rejection is now moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §101 is respectfully requested.

IV. THE ART REJECTIONS ARE OVERCOME

Claims 1-3 were rejected under 35 U.S.C. §102(a) as allegedly being anticipated by non-haemophilliac human blood. Claims 1-3 and 13-15 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Lang et al. (U.S. 5,506,112). The rejections are respectfully traversed and will be addressed in turn.

Turning first to the rejection over non-haemophiliac human blood, the Office Action stated that non-haemophiliac human blood contains factor IXa, factor VIII and phospholipids, and that as the claims recited "comprising", they were read to include non-haemophiliac human blood. It is respectfully submitted that the amendments to the claims herewith have added the recitation that the factor IXa and factor VIII are isolated. Additionally, the claims now recite "consisting essentially of" instead of "comprising". Accordingly, it is respectfully submitted that the claims as currently pending do not read on non-haemophiliac human blood, and the rejection is therefore moot.

Turning now to the rejection over Lang, the Examiner is respectfully submitted that for a Section 102 rejection to stand, the single prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

The Office Action alleges that Lang describes a method where a mixture of factor IXa and phospholipids is added to a factor VIII-containing sample, thus activating factor VIII to be assayed, wherein the activated factor VIII forms a complex with factor IXa. It is respectfully submitted that Lang does not anticipate the present claims because the present invention does not relate to assays for determining factor VIII activity, as are described in Lang. Rather, the present invention relates to two pharmaceutical compositions, one containing coagulation factor IXa, the other containing coagulation factor VIII, which may be administered simultaneously, simultaneously and separately, or sequentially. Therefore, Lang does not anticipate the present claims as it does not contain all of the elements of the present invention.

Specifically, the present invention relates to a first composition consisting essentially of an isolated coagulation factor IXa and a second composition consisting essentially of an isolated coagulation factor VIII, for simultaneous, simultaneous separate or sequential use in the treatment of haemophilia A or haemophilia B in a subject who does not present with anti-FVIII antibodies.

Lang describes only an *in vitro* assay method for determining factor VIII activity. Nothing in Lang describes the use of two compositions that are **administered** to a subject who does not present with anti-FVIII antibodies. Nor is there anything in Lang that describes the use of two compositions for the treatment of haemophilia A or haemophilia B in a subject in need thereof. Furthermore, the compositions of Lang would likely be unsuitable for such a use as they contain a substance such as a tetrapeptide to prevent clot formation during the assay. The use of a composition containing such a substance would be contraindicated for a subject in need of treatment for haemophilia A or haemophilia B.

Therefore, Lang does not contain all of the elements of the claims as there is no description of two pharmaceutical compositions, one containing coagulation factor IXa, the other containing coagulation factor VIII, which may be administered simultaneously, simultaneously and separately, or sequentially.

For all of the reasons set forth above, reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b) is respectfully requested.

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REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview with the Examiner is respectfully requested, and the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the amendments and remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,
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